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profit, provided that such Indian ownership shall constitute not less than 51 percent of the enterprise, and the ownership shall encompass active operation and control of the enterprise.

(e) *Indian reservation* includes Indian reservations, public domain Indian allotments, former Indian reservations in Oklahoma, and land held by incorporated Native groups, regional corporations, and village corporations under the provisions of the Alaska Native Claims Settlement Act (85 Stat. 688, 43 U.S.C. 1601 *et seq.*)

(f) *On or near an Indian Reservation* means on a reservation or reservations or within that area surrounding an Indian reservation(s) where a person seeking employment could reasonably be expected to commute to and from in the course of a work day.

370.204 Compliance enforcement.

(a) The concerned contracting activity shall be responsible for conducting periodic reviews to insure contractor compliance with the requirements of the clauses set forth in 352.270-2 and 352.270-3. These reviews may be conducted with the assistance of the Indian Tribe(s) concerned.

(b) Complaints of noncompliance with the requirements of the clauses set forth in 352.270-2 and 352.270-3 which are filed in writing with the contracting activity shall be promptly investigated and resolved by the contracting officer.

370.205 Tribal preference requirements.

(a) Where the work under a contract is to be performed on an Indian reservation, the contracting activity may supplement the clause set forth in 352.270-3 by adding specific Indian preference requirements of the Tribe on whose reservation the work is to be performed. The supplemental requirements shall be jointly developed for the contract by the contracting activity and the Tribe. Supplemental preference requirements must represent a further implementation of the requirements of section 7(b) of Public Law 93-638 and must be approved by the affected program director and approved for legal sufficiency by the Business and Administrative Law Division, OGC,

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or a regional attorney before being added to a solicitation and resultant contract. Any supplemental preference requirements to be added to the clause in 352.270-3 shall be included in the solicitation and clearly identified in order to insure uniform understanding of the additional requirements by all prospective bidders or offerors.

(b) Nothing in this part shall be interpreted to preclude Tribes from independently developing and enforcing their own tribal preference requirements. Such independently developed tribal preference requirements shall not, except as provided in paragraph (a) of this section, become a requirement in contracts covered under this subpart 370.2, and must not conflict with any Federal statutory or regulatory requirement concerning the award and administration of contracts.

Subpart 370.3—Acquisitions Involving Human Subjects

370.300 Scope of subpart.

This subpart applies to all research and development activities involving human subjects conducted under contract (see 45 CFR 46.102(d) and (f)).

370.301 Policy.

It is the policy of the Department of Health and Human Services (DHHS) that no contract involving human subjects shall be awarded until acceptable assurance has been given that the activity will be subject to initial and continuing review by an appropriate Institutional Review Board (IRB) as described in DHHS regulations at 45 CFR 46.103. An applicable Multiple Project Assurance (MPA) or Single Project Assurance (SPA), approved by the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH), shall be required of each contractor, subcontractor, or cooperating institution having responsibility for human subjects involved in performance of the contract. The OPRR, NIH, is responsible for negotiating assurances covering all DHHS-supported or DHHS-conducted activities involving human subjects. Contracting officers shall be guided by OPRR regarding nonaward or termination of a contract due to inadequate assurance or breach

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of assurance for protection of human subjects.

370.302 Types of assurances.

Assurances may be one of two types:

(a) *Multiple Project Assurance (MPA)*. An MPA describes the oversight procedures applicable to all DHHS-supported human subjects activities within an institution having a significant number of concurrent projects. An MPA listed in OPRR's current "List of Institutions Which Have an Approved MPA" will be considered acceptable for purposes of this policy.

(b) *Single Project Assurance (SPA)*. An SPA describes the oversight procedures applicable to a single DHHS-supported human subjects activity. SPAs may be approved in modified form to meet unusual requirements. SPAs are not solicited from institutions with OPRR approved MPAs. Copies of proposals selected for negotiation and requiring one or more SPAs shall be forwarded to the Human Subjects Assurance Branch, OPRR, NIH MSC 7507, 6100 Executive Blvd., Room 3B01, Rockville, Maryland 20892, as early as possible so that timely action may be taken to secure the SPA(s).

370.303 Notice to offerors.

(a) Solicitations shall contain the notice to offerors in 352.270-8(a) whenever contract performance is expected to involve human subjects.

(b) IRB approval of proposals submitted by institutions having an OPRR-approved MPA should be certified in the manner required by instructions for completion of the contract proposal; or by completion of a DHHS Form 310, Protection of Human Subjects Assurance Identification/Certification/Declaration; or by letter indicating the institution's OPRR-assigned MPA number, the date of IRB review and approval, and the type of review (convened or expedited). The date of IRB approval must not be more than 12 months prior to the deadline for proposal submission.

(c) SPAs for contractors, subcontractors, or cooperating institutions generally will not be requested prior to determination that a contract proposal has been selected for negotiation. When an SPA is submitted, it provides cer-

tification for the initial contract period. No additional documentation is required. If the contract provides for additional years to complete the project, the noncompetitive renewal proposal shall be certified in the manner described in the preceding paragraph.

370.304 Contract clause.

The clause set forth in 352.270-8(b) shall be inserted in all solicitations and resultant contracts involving human subjects.

Subpart 370.4—Acquisitions Involving the Use of Laboratory Animals

370.400 Scope of subpart.

This subpart applies to all research, research training and biological testing activities involving live vertebrate animals conducted under contract (see Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), Rev. 1986, Repr. 1996).

370.401 Policy.

(a) It is the policy of the Department of Health and Human Services (DHHS) and the Public Health Service agencies that no contract involving live vertebrate animals shall be awarded until acceptable assurance has been given that the activity will be subject to initial and continuing review by an appropriate Institutional Animal Care and Use Committee (IACUC) as described in the PHS Policy at IV. B. 6. and 7. An applicable Full Animal Welfare Assurance or Interinstitutional Agreement/Assurance, approved by the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH), shall be required of each contractor, subcontractor, or cooperating institution having responsibility for animal care and use involved in performance of the contract (see PHS Policy II., IV. A., and V. B.).

(b) The OPRR, NIH, is responsible for negotiating assurances covering all DHHS/PHS-supported or DHHS/PHS-conducted activities involving the care and use of live vertebrate animals. Contracting officers shall be guided by